

2. The Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

Claims 45-53 were rejected under 35 U.S.C. § 112, first paragraph, because, according to the examiner, the specification “while being enabling for dicotyledonous plant cells comprising and expressing an isolated nucleic acid encoding for a mammalian peptide, does not reasonably provide for enablement for other types of plant cells”. Office Action at page 3. To facilitate prosecution, Applicants have amended claims 45-47 and 49 to specifically recite dicotyledonous plant cells. As such, the rejection of claims 45-53 under 35 U.S.C. § 112, first paragraph, has been rendered moot by the foregoing claim amendments. Reconsideration and withdrawal of this rejection are respectfully requested.

3. The Rejection of Claims 52-53 Under 35 U.S.C. § 112, Second Paragraph

The examiner has rejected claims 52 and 53 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Office Action at page 6. Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the specification. *See in re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). A person of ordinary skill in the art would understand the metes and bounds of the claims read in light of the disclosure of the specification.

The examiner contends the phrase “physiological effect” as used in the above referenced claims is indefinite because “many different aspects of mammalian physiology may be affected by the ingestion of a peptide, and because the nature of the effects depends on the nature of the peptide ingested.” Office Action at page 6. The examiner also contends that the phrase “regulation of digestive function” is indefinite as recited in claim 53 because “many different aspects of digestive function may be affected by the ingestion of a peptide, because digestive function may be regulated in a variety of different ways, and because the type of regulation and the nature of the function regulated depend on the nature of the peptide ingested.” *Id.* However, the meaning of “physiological effect” and “regulation of digestive function” are clear to one of ordinary skill in the art when read in light of the specification.

The specification states that where the mammalian protein product “can have a physiological effect on ingestion, it may be sufficient that the product be retained with the plant. This will be true where the plant part is edible, such as fodder which could include nutritional qualities, such as bovine growth hormone, seed, nuts, fruit, and vegetables, which could include proteins involved in the regulation of digestion or the like.” Specification at page 9, line 34 through page 10, line 4. One skilled in the art could clearly ascertain the metes and bounds of claims 52 and 53 by the disclosure in the present specification. Simply because, as the examiner contends, “many different aspects of mammalian physiology may be affected by the ingestion of a peptide” and “many different aspects of digestive function may be affected by the ingestion of a peptide” does not render the claims indefinite. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (C.C.P.A. 1971). If the scope of the subject matter embraced by the claims is clear, and if Applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. MPEP§ 2173.04 at page 2100-195.

As such, the rejection of claims 52 and 53 under 35 U.S.C. § 112, second paragraph, is improper. Reconsideration and withdrawal if this rejection are respectfully requested.

4. The Rejection of Claims 45-61 for Double Patenting

Applicants note that claims 45-61 were rejected under the judicially created doctrine of obviousness-type double patenting over: (a) claims 10 and 11 of U.S. Patent No. 6,096,547; (b) claims 1-8 of U.S. Patent No. 5,629,175; (c) claims 1-5 of U.S. Patent No. 5,550,038; and (d) claims 1-3 of U.S. Patent No. 4,956,282. As the Examiner has indicated that claims 45-61 are free of the prior art and are otherwise allowable, Applicants submit herewith a terminal disclaimer with regard to U.S. Patent Nos. 6,096,547; 5,629,175; 5,550,038; and 4,956,282. Accordingly, Applicants respectfully request that the rejection be withdrawn.

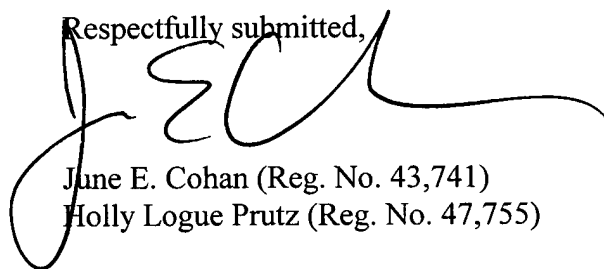
Conclusion

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the

outstanding rejections of the claims and to pass this application to issue. The Examiner is encouraged to contact the undersigned at 202.942.5071 should any additional information be necessary for allowance.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in the documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account Number 50-2387, referencing docket number 18337.005. Applicants likewise authorize a charge to Deposit Account Number 50-2387 for any other fees related to the present application that are not otherwise provided for in the accompanying documents.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to be 'JEC', is written over the typed names.

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Marked-up Version of Amended Claims

45. (Amended) Plant matter comprising dicotyledonous plant cells that express a mammalian peptide.

46. (Amended) The plant matter according to claim 45, wherein said dicotyledonous plant cells are seed cells.

47. (Amended) The plant matter according to claim 45, wherein said dicotyledonous plant cells are rapeseed cells.

49. (Amended) The plant matter according to claim 45, wherein said dicotyledonous plant cells are tobacco plant cells.

54. (Amended) Dicotyledonous plant cells **[having an integrated sequence]** comprising: a first expression cassette having as operatively linked components in the direction of transcription (1) a first transcriptional and translational initiation region functional in said dicotyledonous plant cells, (2) a first structural gene coding for a mammalian peptide, and (3) a first termination region, whereby said dicotyledonous plant cells express said first structural gene.

55. (Amended) The dicotyledonous plant cells according to claim **[54] 72**, wherein said integrated sequence further comprises a second expression cassette having as operatively linked components in the direction of transcription (1) a second transcriptional and translational initiation region functional in said dicotyledonous plant cells, (2) a second structural gene coding for a second peptide which allows for selection of plant cells expressing said second peptide, and (3) a second termination region.